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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,570	01/23/2004	Pamela M. Drake	340082.401	4880

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EXAMINER	
BARNHART, LORA ELIZABETH	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 01/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/763,570	DRAKE ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,7,11 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,7,11 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The reply received 11/15/05 amending claims 1, 7, 11; canceling claims 3, 6, 9, 10, and 12-16; and adding claim 27 is acknowledged. Claim 8 remains withdrawn. Claims 1, 2, 4, 5, 7, 11, and 27 are currently pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Prior art references can be found in a prior Office action, unless otherwise noted.

Specification

The objections to the specification are withdrawn in light of the submission of a substitute specification. The examiner agrees that no new matter has been introduced in this substitute specification.

Claim Objections

Claim 7 remains objected to for formalities. The examiner notes the various amendments to claim 7 with regard to the spelling and format of the bacterial species names; however, the word "thermophilus" is still misspelled at line 2. Correction is requested.

Claim Rejections - 35 USC § 112

Claims 1, 2, 4, 5, 7, 11, and 27 are/remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing in that it is drawn to a composition of matter, but it recites method steps (*i.e.*, "wherein the bacteria are purified or isolated"). Clarification is required. Applicant is urged to amend the claim to recite "A kit

comprising a biologically pure culture of bacteria, a nutrient for bacteria, and an antimicrobial agent," or the like.

Claim 1 is further confusing in that it comprises bacteria and a nutrient for bacteria, but it is not clear whether the recited nutrient must necessarily be a nutrient for the bacteria within the claimed composition, or whether it may be any compound that may be a nutrient to any bacteria. Clarification is required.

Because claims 2, 4, 5, 7, 11, and 27 depend from indefinite claim 1 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim 11 recites the limitation "liquid medium" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite a liquid medium. Clarification is required.

Claim 27 recites the limitation "solid medium" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite a solid medium. Clarification is required.

Claim Rejections - 35 USC § 101

The rejection under 35 U.S.C. § 101 is withdrawn in light of the claim amendments.

Claim Rejections - 35 USC § 102

Claim 1 remains rejected under 35 U.S.C. 102(b) as being anticipated by Gatto et al. (1998, *Journal of Biological Chemistry* 273: 10578-10585). The claim is drawn to a composition comprising bacteria, a bacteria nutrient (which, in this case, has been interpreted as meaning, "a nutrient for bacteria"), and an

antimicrobial agent. Gatto et al. teach *E. coli* cells growing on LB nutrient agar that comprises kanamycin (page 10579).

Applicant alleges that the Gatto et al. reference "nowhere discloses the kit of the presently claimed invention, or even a kit of any kind" (Remarks, page 9, paragraph 4). This argument has been fully considered, but it is not persuasive.

M.P.E.P. § 2112 recites, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established." *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

Claim 1 is drawn to a composition comprising three specific components: bacteria, a nutrient for bacteria, and an antimicrobial agent. The fact that applicant chooses to name the claimed composition a "kit" is irrelevant, because Gatto et al. indeed teach a composition comprising these three specific components. As discussed above and on the previous Office action, Gatto et al. teach a composition comprising bacteria (*E. coli*), a nutrient for bacteria (LB

agar), and an antimicrobial agent (kanamycin). As such, the composition of Gatto et al. anticipates the instantly claimed composition.

Claim Rejections - 35 USC § 103

Claims 1, 2, 4, 5, 7, 11, and 27 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Farmer (2003, U.S. Patent 6,645,506). The claims are drawn to a composition comprising bacteria, a nutrient for bacteria, and an antimicrobial agent. In some dependent claims, the antimicrobial agent is antifungal, in particular nystatin. In some dependent claims, the nutrient is a fructooligosaccharide (FOS). In some dependent claims, the bacteria are a specific mixture of six bacterial species and are prepared via filtration from their culture media.

Farmer teaches therapeutic compositions comprising *Bacillus coagulans* and fructooligosaccharide (column 25, line 57, through column 26, line 25; "Formulation 1"). Farmer teaches that said composition may also comprise one or more of numerous probiotic bacteria (column 21, line 63, through column 22, line 27). Farmer teaches that the composition may further comprise an antimicrobial agent, for example an anti-fungal compound such as nystatin (column 22, lines 28-51, especially line 45).

The selection of probiotic bacteria to be included in the composition of Farmer clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Farmer teaches that the bacteria may be one or more of any of numerous probiotic bacteria and that the recited bacteria are art-accepted equivalents column 2, lines 21-32). A holding of

obviousness over the cited claims is therefore clearly required. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

While Farmer does not explicitly teach a composition comprising a mixture of probiotic bacteria, the inclusion of multiple different strains (as required in instant claim 7) does not render the instant composition patentable. Farmer specifically contemplates compositions comprising multiple strains (column 2, lines 19-22). In addition, it is well established that duplicating components with similar functions within a composition is obvious; see *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) and M.P.E.P. § 2144.04.

Claims 11 and 27 are product-by-process claims. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps." As such, the requirement that the bacteria be prepared by filtration has been considered only to the extent that it affects the structural properties of the bacteria resulting from said preparation. In any case, Farmer teaches preparing bacteria by filtration (column 14, lines 50-57).

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was

made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

A person of ordinary skill in the art would have had a reasonable expectation of success in including nystatin in the composition of Farmer because Farmer specifically contemplates such an addition; at column 21, lines 55-62, Farmer suggests a composition comprising probiotic bacteria and an anti-fungal compound. **The skilled artisan would have been motivated to include nystatin in the composition of Farmer for the expected benefit that fungal infections might be prevented by the administration of said composition.**

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute one or more of the bacteria at columns 21-22 into the exemplified composition of Farmer because Farmer teaches that the bacteria are art-accepted substitutes. It would have been further obvious for the artisan to add nystatin to the composition of Farmer because Farmer teaches that the inclusion of antifungals in bacterial compositions retards the growth of yeast and molds (column 5, line 62, through column 6, line 12).

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant alleges, "nowhere in the cited [Farmer] reference is a kit claiming the present invention even remotely contemplated" (Remarks, page 10, paragraph 2). Applicant further alleges that the examiner did not provide motivation to modify the invention of Farmer (Remarks, page 10, paragraph 3). Applicant further alleges that Farmer "does not explicitly teach a composition comprising a mixture of probiotic bacteria" (Remarks, page 10, paragraph 4). These arguments have been fully considered, but they are not persuasive.

First, as discussed above, the fact that applicant chooses to name the claimed composition a "kit" is irrelevant, because Farmer indeed teaches a composition comprising these three specific components. As discussed above and on the previous Office action, Farmer teaches a composition comprising bacteria (*B. coagulans*), a nutrient for bacteria (fructooligosaccharide), and an antimicrobial agent (Nystatin). The composition of Farmer therefore renders the instantly claimed composition obvious.

The examiner did, in fact, provide motivation to modify the composition of Farmer with any bacteria, nutrient, and antimicrobial agent. To allay this point of confusion, the examiner's motivation statement has been placed in **bold** above. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art (which the examiner doe not concede) cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Regarding applicant's assertion that Farmer does not teach "a composition comprising a mixture of probiotic bacteria," the examiner points out that the claims do not recite a composition that comprises a mixture of probiotic bacteria. In any case, Farmer clearly contemplates compositions comprising more than one bacterium (column 2, lines 19-22).

Claims 1, 2, 5, 11, and 27 also remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over van Lengerich et al. (2001, U.S. Patent

6,190,591). The claims are drawn to a composition comprising bacteria, a nutrient made by bacteria, and an antimicrobial agent. In some dependent claims, the antimicrobial agent is antifungal. In some dependent claims, the bacteria are produced by filtration.

van Lengerich et al. teach a controlled-release capsule comprising a pharmaceutical component (Examples 1-9). van Lengerich et al. teach that the composition may comprise any of numerous compounds (columns 9-14), including those produced by bacteria (including penicillin; column 12, line 2), those that might be consumed by bacteria (column 9, lines 1-22), and any of numerous antifungal agents (including nystatin; column 11, line 60). van Lengerich et al. further teach that the composition may comprise probiotic bacteria (column 9, lines 34-42).

A person of ordinary skill in the art would have had a reasonable expectation of success in adding probiotic bacteria, compounds produced by bacteria, or antifungal agents to the capsules of van Lengerich et al. because van Lengerich et al. teach that the capsules may comprise any pharmaceutical or therapeutic compound (column 9, lines 19-32). **The skilled artisan would have been motivated to include bacteria, bacterial compounds, and antifungals for the expected benefit that upon administration, the capsules would deliver mold-free bacteria to the digestive system.**

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to add bacteria, bacterial compounds, or

antifungals to the capsules of van Lengerich et al. because van Lengerich et al. teach that any or all of these may be incorporated into said capsules.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant alleges that the examiner did not provide motivation to modify the invention of van Lengerich et al. (Remarks, page 11, paragraph 2). Applicant further alleges that van Lengerich et al. "provides a generalized laundry list of potential antibiotics that could possibly be included in any pharmaceutical composition but does not even remotely contemplate the kit of the presently claimed invention (Remarks, page 11, paragraph 3). These arguments have been fully considered, but they are not persuasive.

The examiner did, in fact, provide motivation to modify the composition of van Lengerich et al. with any bacteria, nutrient, and antimicrobial agent. To allay this point of confusion, the examiner's motivation statement has been placed in **bold** above. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art (which the examiner doe not concede) cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Patents are relevant as prior art for all they contain. "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33,

216 USPQ 1038, 1039 (Fed. Cir. 1983). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Nonpreferred embodiments constitute prior art. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). See M.P.E.P. §2123. In this case, the fact that van Lengerich et al. disclose numerous embodiments that are not necessarily preferred embodiments does not imply that the reference does not teach these embodiments.

As discussed above, the fact that applicant chooses to name the claimed composition a "kit" is irrelevant, because van Lengerich et al. indeed teach a composition comprising these three specific components. As discussed above and on the previous Office action, van Lengerich et al. teaches a composition comprising bacteria (probiotic bacteria), a nutrient for bacteria (for example, the components at column 9, lines 1-22), and an antimicrobial agent (penicillin or nystatin). The composition of van Lengerich et al. therefore renders the instantly claimed composition obvious.

No claims are allowed. No claims are free of the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart

LEB

SANDRA E. SAUCIER
PRIMARY EXAMINER